

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
) Phoenix, Arizona
) March 16, 2018
)
Sherr-Una Booker, an individual,)
) Plaintiff,) CV-16-00474-PHX-DGC
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral)
Vascular, Inc., an Arizona)
corporation,)
) Defendants.)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 3 P.M. SESSION

(Pages 580 – 654)

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DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

PROCEEDINGS

(Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. O'Connor.

MR. O'CONNOR: Thank you, Your Honor.

ROBERT McMEEKING,

recalled as a witness herein, after having been previously
duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N (CONTINUED)

BY MR. O'CONNOR:

Q Mr. McMeeking, was there something you needed to clarify about the fracture of the G2 filter that Sheri Booker experienced?

A Yes. I misspoke. There were three fractures, but only two struts were involved. So one of the struts broke twice. But I misspoke when I described that.

O All right.

Now, let's talk about fracture. We touched on it before but, if you could, why does the G2 fracture after -- I think you said it can get itself in a tilted, perforating position.

A Correct. And it's the perforation that is particularly important in that regard. And I can demonstrate it by using

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:04:25 1 my ruler, which I would like you to imagine is one of the
2 struts of the filter, and so it's being held at the top by the
3 cap and it's attached to the wall of the vena cava down here.
4 Now, I know that the limbs of the filter are not straight and
13:04:45 5 not the shape that the ruler is, but this is just to help you
6 see what I'm trying to describe.

7 So when the vena cava expands and contracts, it does
8 so by a specific amount, and I'm going to say that that's,
9 say, a couple of inches at the bottom. Of course that is
13:05:06 10 exaggerated compared to what goes on in the vena cava. So
11 when the vena cava expands, the bottom of the ruler moves out
12 two inches. And you see that it moves relative to my hand.
13 And that's a process that causes strain in the strut.

14 I think you would also understand clearly that if I
13:05:30 15 move the arm or the strut a lot, the strain which is involved
16 will be a lot. Okay?

17 So the situation when the filter is not perforated is
18 that it moves with the wall of the vena cava by a certain
19 amount.

13:05:48 20 Now let's imagine that the strut has perforated the
21 wall of the vena cava so that the wall of the vena cava is now
22 there. The wall is still going to move by the same amount and
23 so it moves, say, an inch. But you notice that the end of the
24 ruler moved a lot more. And so the process of perforation
13:06:10 25 increases the motion of the strut and it increases the strains

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:06:17 1 which the strut experiences. And this leads directly to an
2 enhancement of the process of fatigue, which will damage the
3 strut and eventually make it break. And so perforation
4 contributes to the fracture problem in that manner.

13:06:35 5 Q In this case did you determine that there was a design
6 flaw, a defective design in the G2 that was responsible for
7 the limbs that fractured in the Sheri Booker G2 filter?

8 A Yes. Because in her filter, many of the limbs perforated
9 the wall of the vena cava.

13:06:53 10 Q And then when they perforated, that in turn caused the
11 fracture?

12 A That would in turn cause the fracture.

13 Q And so to summarize that, when the limbs perforate the IVC
14 wall, will that cause further tilt?

13:07:14 15 A Yes. I think you could see that in the diagram, which I
16 can show again. In fact, it would be useful to show 4347 to
17 illustrate.

18 Q Forty --

19 A 4347.

13:07:31 20 Q 4347?

21 MR. O'CONNOR: May we display it, Your Honor, for
22 Dr. --

23 THE COURT: Yes.

24 MR. O'CONNOR: -- McMeeking?

13:07:39 25 THE COURT: Yes.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:07:40 1 MR. O'CONNOR: Thank you, Your Honor.

2 BY MR. O'CONNOR:

3 Q So, Dr. McMeeking, what is being displayed here, and how
4 does this help explain your opinions to everyone that's here
13:07:49 5 in the courtroom?

6 A Well, you can see that what I'm showing here is a filter
7 which has one leg perforated, and it's gone out of the vena
8 cava to some extent, but not that much. And although it's
9 perhaps hard to see, you can see that the filter has tilted
13:08:07 10 just a little bit.

11 Now, if we, if we look at illustration 4349, please.

12 Q 4349.

13 A You can see that the -- in this case, which I showed you
14 before, the perforation has developed to a greater extent, and
13:08:34 15 as consequence there's a lot more tilting which is present in
16 the filter.

17 So perforation leads to tilt and tilt leads to
18 perforation, and together they can contribute to increased
19 likelihood of fracture by fatigue.

20 Q When the G2 tilts and perforates, I think you told us it's
21 more prone to fracture. Does it also have an impact on
22 adjoining anatomical structures?

23 A When the limbs of the filter are outside of the vena cava,
24 they can interfere with neighboring organs.

25 Q Earlier, you talked about calculations that you had

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:09:16 1 performed, and you went over them generally. Can you tell us
2 in simple terms what went into the calculations that you
3 performed to analyze things like fatigue failure.

4 A So, for example, let's use the illustration which is still
13:09:38 5 visible. I made use of the shape of the limbs. And let's
6 focus on the arm. I took into account the shape of the limb
7 and used that in my calculation. I used the properties of the
8 material, which is Nitinol. I used the amount by which the
9 vena cava expands and contracts, and I put those into a
13:10:09 10 mathematical calculation which uses -- balances the forces and
11 tracks the deformations which occurred in the filter, although
12 this is not the kind of -- this is not a filter limb. The
13 kind of deformation I'm talking about is when I bend this
14 ruler.

13:10:31 15 So the calculation I did would relate to what my
16 fingers are doing to the ruler, to how much bending will take
17 place. So the connection is the same in the calculation for
18 the limb. I look at how much motion is being imposed on it,
19 and I look at how much bending is being -- is taking place in
13:10:50 20 the limb.

21 Q So you could take the shape of the material, the length,
22 the dimension, and the properties of the material, and there
23 are math- -- mathematical equations that engineers are trained
24 to perform?

13:11:08 25 A Yes, sir. There are mathematical methods. The one that I

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:11:10 1 used specifically is called Euler-Bernoulli beam theory. I
2 know it's a bit of a mouthful, but it's something we teach to
3 second-year and third-year mechanical engineers, and it is
4 commonly used in the practice of mechanical engineering, such
13:11:25 5 as what I do.

6 In addition, I did, from that element, computer
7 calculations. And so I essentially did the same kind of
8 calculation, but instead of doing it on a piece of paper, I
9 did it in the computer. But the two calculations were -- had
13:11:44 10 the same objective and the same methodology.

11 Q What was the first one called?

12 A The first one was called Euler-Bernoulli beam theory.
13 E-U-L-E-R, hyphen, B-E-R-N-O-U-L-L-I.

14 Q That's what I thought you said.

13:12:05 15 And those are basic engineering calculations?

16 A Yes.

17 Q And when you do a calculation like that, how long does
18 that take?

19 A Well, the Euler-Bernoulli beam theory calculation took me
13:12:15 20 about 15 minutes to half an hour.

21 Q And how many of those do you do to arrive at your opinions
22 in this case?

23 A Well, I did hundreds of them in the sense of producing
24 hundreds of results. Maybe not hundreds, but certainly dozens
13:12:26 25 of results. And some of them were more complex than others,

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:12:30 1 so some took a bit longer than 15 minutes to half an hour.

2 Q And how do you decide on a calculation? Are there certain
3 assumptions that you take, and then you apply a calculation to
4 them?

13:12:43 5 A Yes. As I mentioned before, one needs to know the
6 environment in which the filter will function, and that means
7 knowing something about what the vena cava will do, expanding
8 and contracting. One needs to know what sort of stiffness of
9 the tissue and organs around it, what sort of influence that
13:13:05 10 they would have on the behavior. And the kind of events that
11 the vena cava will experience while the filter is in it.

12 Q If a company like Bard wanted to check its calculations
13 and to confirm that it made the correct assumptions about the
14 anatomy and the environment, and also that it was complying
13:13:27 15 with what you have told us should be complied with, the worst
16 case, are there people like you, professors in engineering,
17 that can help companies like that?

18 A Yes.

19 Q And has that ever happened to you?

13:13:39 20 A Well, I've consulted for medical implant companies many
21 times where I've carried out calculations for them, both
22 assessing the worst case conditions that they should consider
23 and actually carrying out the calculations and providing them
24 with the results.

13:13:53 25 Q I mean, are some of these calculations that you, with your

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:13:56 1 training, can do by hand?

2 A Yes, some of them were calculations I did by hand. Some
3 are calculations I did by computer.

4 Q And those calculations will tell you what when it comes to
13:14:09 5 fatigue?

6 A Those calculations will tell me and the company how big
7 the strains are, and if the strains are too big, then that
8 will indicate that fracture by fatigue is going to happen.

9 Q So are you saying that you can take the G2 filter, look at
13:14:29 10 the legs, the length, take the material and the dimensions and
11 the thickness, and then determine what conditions will be
12 imposed upon the filter after it's in the vena cava, and you
13 can calculate that and predict under -- when and how it will
14 fracture?

15 A Well, I can predict the stresses and strains which will
16 occur, and I can then use that to compare with data on the
17 material that tells us whether the device will last a long
18 time, whether it may last only a short time under the
19 conditions imposed.

20 Q Now, based upon the work you did in this case and the way
21 you learned that tilt can lead to changes in forces, and then
22 also lead to other complications, did you determine to a
23 reasonable degree of engineering probability that the
24 complications are interrelated in the G2 filter?

25 A Yes.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:15:47 1 Q And tell us what you did and what your opinion is.

2 A What I did is I looked at how tilt will lead to
3 perforation, how perforation will lead to tilt, and how both
4 of those can lead to fatigue fracture, and I used
13:16:04 5 considerations of worst case conditions to come to that
6 conclusion.

7 Q Now, can you show us the filter and show us what it is
8 about the design of the G2 that will result in that cascade
9 where one will lead to another.

13:16:24 10 MR. O'CONNOR: Your Honor, I asked Mr. North. We put
11 up a portable Elmo to enlarge it. Would that be permissible
12 for him to show under that?

13 MR. NORTH: That's fine, Your Honor.

14 THE COURT: Yeah, that's fine.

13:16:36 15 MR. O'CONNOR: I think we need --

16 MR. WOODY: Witness HDMR.

17 THE COURTROOM DEPUTY: Witness HDMR.

18 MR. O'CONNOR: You're on this Elmo.

19 There we go.

13:17:01 20 THE WITNESS: So here's the G2 filter, and it's --
21 essentially it's conical shape.

22 BY MR. O'CONNOR:

23 Q I think you've got to move it up or down, because I get
24 disoriented under these things.

13:17:13 25 MR. WOODY: Mark, I could help him set it up?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:17:16 1 MR. O'CONNOR: Your Honor, may our IT assist- --

2 THE COURT: What do we need to do?

3 MR. WOODY: Set it up better so he gets a clearer
4 image.

13:17:26 5 THE COURT: Yeah, that's fine.

6 MR. WOODY: I think a white piece of paper would be
7 better.

8 THE WITNESS: So it's the conical design that leads
9 to this defective condition, because the arms and the legs are
13:18:05 10 all connected together into the cap where my -- where I'm
11 holding it by my fingers.

12 BY MR. O'CONNOR:

13 Q And that's where the arms and legs emanate from; right?

14 A That's right. They all come out of the cap, just below my
15 finger. And you can just see it between my fingers. And the
16 fact that it functions as a spring makes it want to tilt. It
17 makes it want to perforate the wall of the vena cava because
18 the arms and legs are coupled together at the cap and because
19 the legs are not stiff enough to inhibit the arms when they
13:18:43 20 want to tilt and the arms are not stiff enough to inhibit the
21 legs when they want to tilt. As a consequence it will
22 perforate, and as a consequence these phenomena take place,
23 and that leads to the cascade of events that can cause the
24 fracture by fatigue.

13:19:03 25 Q Could Bard have designed this filter differently to avoid

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:19:06 1 these complications and the cascade?

2 A Yes.

3 Q How?

4 A Well, for example, they could have made it more like an
13:19:14 5 existing filter, which is the Bard -- sorry, the Simon Nitinol

6 filter, which I can show on the screen as well. And -- that's
7 this filter here. And you can see it's got a different shape.

8 And the features of this filter that make it advantageous are

9 that the umbrella basket, the clot-trapping basket at the top,

13:19:47 10 has a large area of contact with the wall of the vena cava.

11 That means it's less likely to perforate through the wall of
12 the vena cava.

13 The struts are stiffer in general compared to the G2
14 and the Recovery filter, and that means that when it's
13:20:13 15 squeezed into a vena cava of a given size, it is less likely
16 to migrate.

17 In addition, the fact that it has a two-component
18 design -- and I'm referring to the fact that up at the top
19 there's this basket which can help to trap clots, and down
13:20:34 20 below are the legs, but you notice that they're connected
21 through a junction -- which I'm pointing at, maybe you can see
22 it a little better -- but what that means -- if I hold it this
23 way -- but what that means is there's a decoupling between the
24 bottom half of the filter and the top half of the filter.

13:20:55 25 What that means is that if the basket wants to tilt,

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:21:01 1 it is not likely that it's going to take the legs with it. If
2 the legs want to tilt, it is less likely that it will take the
3 basket with it.

4 In addition, if the legs perforate, because of the
13:21:16 5 way the strains develop, it is less likely that fatigue
6 fracture is going to occur in the legs, and it is very
7 unlikely that fatigue fracture is going to occur in the
8 basket.

9 In addition, if fracture does occur in the basket at
13:21:37 10 the top -- and I'm sorry, I'm hiding it -- if you notice, that
11 because the wires are looped around from a top cap to a sleeve
12 in the middle, the piece of metal that breaks is not going to
13 be lost to the filter and will sit in place just with a broken
14 wire sitting there.

13:22:00 15 And another point is that when the -- if the basket
16 tilts, then it looks like it will still function well as a
17 clot-trapping feature.

18 And so all of these things to me, as an engineer, add
19 up the concept that this is a better and safer filter.

13:22:20 20 Q All right. Dr. McMeeking, I want to just touch on just a
21 moment with you. You are aware that Bard has retained its own
22 expert engineer in this case?

23 A Yes, I am.

24 Q And can you just explain, what are the differences between
13:22:36 25 the calculations you performed and the calculations that

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:22:39 1 Dr. Briant performed?

2 A Dr. Briant has performed calculations in the same way as
3 I've done them, but he has used different assumptions to get
4 to his results. And the assumptions that he uses are often
13:22:54 5 such that he's in best case conditions, are certainly not in
6 worst case conditions. Whereas my assumptions, I always try
7 to make sure are going to establish the worst case conditions
8 in the calculations.

9 Q And from what you've seen in your work in this case, if

13:23:15 10 the worst case conditions had been done, would Bard have known
11 that the G2 would do what it's done? For example, in this
12 case where it's migrated, perforated -- tilted, perforated and
13 fractured?

14 A Yes, they would have been aware of that.

13:23:32 15 Q Let's talk about Bard's testing. Did you review Bard's
16 testing and its engineering analyses for the Recovery and the
17 G2 filters?

18 A Yes, I did.

19 Q Did you review Bard's bench test?

13:23:43 20 A Yes.

21 Q What about Bard's finite element test, did you review
22 those?

23 A I reviewed that, yes.

24 Q Both for the Recovery and the G2?

13:23:50 25 A Both the Recovery and the G2.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:23:51 1 Q And do you have an opinion whether testing that Bard did
2 was reasonable?

3 A No, the testing was not reasonable.

4 Q And was the testing adequate?

13:23:59 5 A It was not adequate.

6 Q Did the test that Bard performed on the Recovery and G2,
7 did they conform with standards for reliable and safe designs?

8 A No, they did not because -- because they didn't carry out
9 tests that would have established all of the failure modes
13:24:21 10 which were likely to occur in the filter, and the test that
11 they did carry out did not impose worst case conditions on the
12 filter during those tests.

13 Q Do you have any examples?

14 A Well, for example, in the -- they carried out a fatigue
13:24:40 15 test and what they did was that they put --

16 Q Again, that's a test that tests for fracture?

17 A That's a test for fracture.

18 So they took the Recovery filter -- I don't have an
19 example of the Recovery filter, but it's quite similar as
13:24:55 20 detailed differences in shape compared to the G2 filter. But
21 they put a Recovery filter in a tube, which was approximately
22 19 millimeters in diameter, so it's similar to the diameter of
23 a vena cava, and they squeezed the tube by a change of
24 diameter of one millimeter. One millimeter is the thickness
13:25:20 25 of a penny. And 19 millimeters is about three quarters of an

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:25:26 1 inch.

2 So they took the tube and squeezed it by one
3 millimeter. They allowed it to expand again by one
4 millimeter. And the -- this was to simulate what happens to
13:25:39 5 the filter when it's in the vena cava.

6 However, they put the filter in so that it was not
7 tilted, they put the filter in so that it was not perforated,
8 and they put the filter in so that it was not endothelialized
9 to the wall of the vena cava.

13:26:01 10 Q Meaning what?

11 A Endothelialization is a process by which tissue grows over
12 implants and other things in the body and essentially glues
13 the object to the tissue in the human body. And that would --
14 all of the things I just described would make sure that you
13:26:23 15 were looking at worst case conditions in the test.

16 Q Now, let me ask you this about the Recovery and the bench
17 testing that was done: Did you review that?

18 A I did, yes.

19 Q And did you review fatigue tests that were done on the
13:26:38 20 bench for the Recovery?

21 A Yes. So I -- that's the test I was just describing.
22 And -- the fracture -- the fracture fatigue test. And they
23 carried it out for 32 million or 36-million cycles of loading.
24 And they represented that -- they stated that that represents
13:27:01 25 ten years of breathing for a patient.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:27:06 1 Q Break that down for us. When you talk about cycles, what
2 are you talking being about?

3 A One cycle is when you squeeze the vena cava by one
4 millimeter and you allow it to expand again by one millimeter.

13:27:18 5 So that is what I'm describing as a cycle. And they imposed
6 32 million or 36 million cycles of such changes of diameter on
7 the tube, and therefore on the filter.

8 Q Well, let me see if we can understand this. So when you
9 talk about cycles, is there a way to impose fatigue on the
13:27:41 10 filter that would replicate how many breaths a person would
11 have over a period of years?

12 A That's correct. So --

13 Q How is that important? Does that affect the vena cava?

14 A Yes. Because when you breathe, that is what causes the
13:27:54 15 vena cava to expand and contract. And you breathe a lot over
16 the years.

17 Q We heard testimony from a Bard engineer yesterday that the
18 Recovery was tested for ten years. Is that accurate?

19 A No. It was not accurate. Certainly not in the sense of a
13:28:12 20 worst case condition.

21 Q Why do you believe it was closer to four years?

22 A Because the calculation that leads you to 32 million
23 cycles in ten years is based on the assumption that you're
24 breathing six times in a minute. That is very slow.

13:28:33 25 Q What is it like? When you're asleep?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:28:35 1 A It's -- it's relevant to when you're asleep.

2 Q What is more realistic?

3 A What is more realistic is 15 breaths per minute, and
4 perhaps even more. But let's use 15 breaths per minute as a
13:28:47 5 reasonable estimate of rate of breathing, and that would lead
6 to 80 million cycles in ten years. And so to do the test to
7 represent ten years of breathing, they should have taken it to
8 80 million cycles.

9 Q Let me ask you this: Did you see any evidence in this
13:29:09 10 case where Bard had a range on that breaths per minute that
11 was between six and another number, 15, like you just said?

12 A Well, I read a deposition by Mr. Chanduszko, and he stated
13 that he and the company understood that the range of the rate
14 of breathing was between six and 15 per minute.

15 Q And let me just stop you there.

16 Six is while we're asleep.

17 A Six is while we're asleep.

18 Q 15 is while we're up, walking, moving, doing everyday
19 activities?

20 A Well, everyday activities, but perhaps not very strenuous
21 activities.

22 Q Okay. And so based upon those two, what did Bard choose
23 to look at?

24 A They chose to look at six breaths per minute, which is the
13:30:03 25 best case that would be present as far as the filter's

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:30:08 1 concerned.

2 Q Was that reasonable?

3 A That was not reasonable. They should have considered the
4 worst case, which I would say would be at least 15 breaths per
13:30:17 5 minute.

6 Q So even if you took 15, would that even be the worst case?

7 A No. Because in strenuous exercise, you breathe faster.
8 So even 15 breaths per minute may not be the worst case.

9 Q If Bard was going to act reasonably and test for the worst
13:30:38 10 case scenario when it came to fatigue, what should it have
11 done with the breathing test?

12 A They should have used at least 15 breaths per minute, and
13 they should have run the test, if it was to represent ten
14 years, for at least 80 million cycles.

13:30:56 15 Q We heard testimony yesterday that Bard test tested the
16 Recovery for 400 mm. Millimeters; is that right?

17 A 400 million cycles.

18 Q 400 million cycles.

19 Have you ever seen such a formal report?

13:31:13 20 A I've never seen a report on results of such a test.

21 Q All right. So if such a test was done at a medical device
22 company, what should anybody that claims that test was done
23 bring to this Court?

24 A There should be proper documentation of the test. There
13:31:26 25 should be proper information about it that would determine

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:31:31 1 whether it was designed properly, whether it was done
2 properly, and whether it was checked thoroughly and reviewed,
3 to make sure that everything was done correctly and that the
4 results were meaningful.

13:31:44 5 Q What other testing did you find was done incorrectly or
6 wrong by Bard?

7 A Well, in the testing of the Recovery, there were a number
8 of tests which were not done. For example, there was no test
9 to look at whether the filter would be prone to tilting. So
13:32:04 10 there was no effort to see whether it would resist tilting.
11 There was no bench test to consider whether the limbs would
12 perforate through the wall of the vena cava. No test in which
13 they tried to determine how likely it was that the limbs would
14 be able to cut through the wall of the vena cava.

13:32:32 15 Q Despite that testing, did the Recovery go to market?

16 A Yes, it did.

17 Q What is a root cause analysis?

18 A A root cause analysis is where you have a problem, a
19 failure, a malfunction, and you investigate the situation to
determine what caused that malfunction or failure.

21 Q Was that ever done? Did you see any evidence of it being
22 done?

23 A Bard attempted to do a root cause analysis in regard to
24 the fractures the Recovery was experiencing, but they never
13:33:03 25 were able to come to a conclusion in terms of a root cause

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:33:08 1 analysis as to why those fractures were occurring.

2 Q And when did they do that? After it was on the market?

3 A They did it after it was on the market.

4 Q Should Bard have known before the Recovery was ever
13:33:20 5 released that it was too dangerous to put out in the market?

6 A Yes. If they had done proper testing and if they'd done
7 properly analysis and if they'd done safe and reliable design,
8 they would have realized that it was a dangerous and defective
9 device that was going to fracture.

13:33:37 10 Q Did you review testing that Bard did for the G2?

11 A I did.

12 Q And what type of testing did you review that Bard did?

13 A I reviewed the bench testing and their calculations.

14 Q And at what conclusions did you arrive?

13:33:54 15 A I came to the conclusions that the testing was inadequate,
16 and that the calculations were also inadequate.

17 Q Did the testing that Bard did for the G2 address the
18 problems that Bard saw and was aware of that were occurring in
19 the Recovery?

13:34:13 20 A No. They did not.

21 Q So what did Bard do by way of testing for G2?

22 A Well, they undertook some calculations, and they used them
23 to avoid doing a bench test to consider the fatigue fracture
24 of the G2. In other words, they redesigned the Recovery to
13:34:40 25 become the G2, and they hoped that they had addressed the

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:34:45 1 problems that the G2 had -- that the Recovery had, and they
2 should have carried out a bench test of a variety of things,
3 such as fracture by fatigue, tilting, perforation of the wall
4 of the vena cava, and tilting. But they did not carry out any
13:35:07 5 of those tests, at least in the context of the kind of
6 expansion and contraction of the vena cava wall. The vena
7 cava that I've been describing.

8 So they omitted a whole lot of tests, and to avoid
9 doing a fatigue test of the expansion and contraction of the
13:35:29 10 vena cava, they carried -- instead they carried out a finite
11 element calculation.

12 Q What was wrong with that?

13 A Well, that's very bad engineering practice because if you
14 have redesigned a device to try to -- to try to reduce
13:35:46 15 failures to -- either to eliminate them or to reduce them to
16 the extent feasible, it is of critical importance to test the
17 device to make sure that the objective has been achieved.

18 It was -- this compounded the fact that they didn't
19 really know what was causing the fractures because their root
13:36:09 20 cause analysis of the Recovery had not revealed exactly why
21 the Recovery was fracturing. And, therefore, they were
22 groping in the dark, as it were, when they redesigned to get
23 the G2, and then they failed to carry out tests that would
24 have properly assessed whether, in fact, they had corrected
13:36:28 25 the problems.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:36:29 1 Q If Bard wanted to step out of the dark and into the light
2 to make G2 safe, and they retained somebody like you, what
3 would you have told them to do by way of testing?

4 A I would have told them to do a worst case test of the
13:36:42 5 expansion and contraction of the vena cava. So, in other
6 words, put in a G2 filter, tilted, perforated, and then
7 endothelialized, and carried out test to the appropriate
8 number of cycles of breathing, such as 80 million cycles or
9 more, to represent ten years.

13:37:07 10 Q Based upon what Bard knew from the Recovery, how difficult
11 would it have been to have those tests performed?

12 A It would not have been difficult. It would have required
13 some design of the tests to get them to work in the way
14 intended, but in principle, the tests could have been
13:37:25 15 undertaken.

16 Q Could a company design a test in a way that it will get
17 best case results when it should be looking for worst case
18 results?

19 A Yes. They can choose to use best case conditions instead
13:37:40 20 of worst case conditions.

21 Q Do you have an opinion whether Bard did that in this case
22 with the G2?

23 A It is my opinion that in the testing process, this is what
24 they did. And in the case of the breathing fatigue test,
13:37:54 25 their best case conditions were implemented by a calculation

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:37:57 1 rather than a bench test. And the calculation didn't account
2 for tilting or perforation.

3 And furthermore, it was not a fatigue cycling
4 calculation. Instead, it was simply a calculation in which a
13:38:12 5 filter is deployed into a vena cava. So that did not address
6 what happens when the vena cava expands and contracts.

7 Q When Bard was working and designing the G2, should it have
8 been designing it in a way that it would eliminate the
9 problems Bard saw in the Recovery?

13:38:29 10 A Yes.

11 Q And could Bard have done the appropriate tests, the
12 appropriate calculations so that the G2 would have reduction
13 in tilt?

14 A Yes.

13:38:41 15 Q How would they have done that?

16 A Well, they would have, of course, redesigned it to
17 eliminate some of the features of the filter that allowed tilt
18 to happen. So, for example, redesigning it to look a bit more
19 like the Simon Nitinol filter, and they could have undertaken
13:39:03 20 other steps that would have controlled the tilting more
21 effectively.

22 Q The calculations that you have determined Bard should have
23 done, that would have eliminated tilt, perforation, and
24 fracture?

13:39:17 25 A Could you repeat the question.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:39:18 1 Q Sure. Have you determined that Bard could have and should
2 have done tests and calculations to eliminate tilt, to
3 eliminate migration, to eliminate perforation, and to
4 eliminate fracture?

13:39:31 5 A Yes.

6 Q How hard would those tests be?

7 A They would not have been difficult. I think they would
8 have been -- certainly the calculations would have been fairly
9 straightforward. The tests, as I said, would have taken some
13:39:43 10 effort to design them properly, but they were certainly
11 manageable tests.

12 Q Are the calculations that needed to be done anything
13 difficult for a Ph.D. like you, or can any -- an engineer
14 trained do those types of calculations?

13:39:59 15 A They're something that is within the ability of an
16 engineer who's graduated with a bachelor of science degree in
17 engineering, and even some undergraduates could carry out the
18 calculations. And certainly with a master's degree in the
19 mechanical engineering, their skill set would have encompassed
13:40:21 20 the kind of things that should have been done.

21 Q Do you have an opinion whether Bard complied with those
22 rules, safety rules, worst case, patient safety being
23 paramount, the things that a reasonable medical device company
24 would do in designing a filter to get rid of or eliminate or
13:40:41 25 reduce known complications from a prior product like the

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13 : 40 : 44 1 Recovery?

2 A In my opinion, they did not carry out that in an
3 appropriate manner.

4 Q And is that opinion, as well as all of the opinions you've
13 : 40 : 53 5 told us about today, are those opinions that you hold to a
6 reasonable degree of engineering probability?

7 A Yes.

8 Q Let me talk to you about one other area here today.

9 Oh, and the way that you went about this process,
13 : 41 : 08 10 Dr. McMeeking, to evaluate the Recovery, to evaluate the G2,
11 did you apply reasonable accepted engineering standards and
12 methods?

13 A Yes. The methods I used are completely standard in
14 mechanical engineering and in design.

13 : 41 : 28 15 Q We heard claims in this case that the G2 is 12 times more
16 fracture resistant than the Recovery.

17 A Yes.

18 Q Have you seen that claim before?

19 A I've seen that claim before.

13 : 41 : 42 20 Q Is that true?

21 A No.

22 Q Why not?

23 A Well, the test that's being referred to is one that was
24 carried out on the G2. So instead of carrying out the fatigue
13 : 41 : 52 25 test where Bard expanded and contracted the vena cava, instead

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:41:57 1 they carried out a fatigue test in the following manner:

2 They took the G2 filter and they, first of all, cut
3 all of its legs off. So --

4 Q Well, hang on, Doctor. Before we get there, I want to
13:42:16 5 show you Exhibit 4375.

6 MR. O'CONNOR: Your Honor, this is something that was
7 displayed in opening. I'd like Dr. McMeeking to talk about
8 this figure.

9 May I publish it to the jury?

10 THE COURT: Is this in evidence?

11 MR. O'CONNOR: No.

12 THE COURT: It needs to be in evidence.

13 MR. O'CONNOR: I would like it for demonstrative
14 purposes.

15 THE COURT: Was this a demonstrative exhibit created
16 for purposes of trial, or is it a document --

17 MR. O'CONNOR: I think this was used by the defense
18 in opening.

19 MR. NORTH: It's a slide from my opening statement,
13:42:56 20 Your Honor. I don't think there's any problem with the graph
21 itself, which comes from a test report, but the slide from the
22 opening I don't think is appropriate.

23 THE COURT: Is this the slide or the graph?

24 MR. O'CONNOR: I would like -- well, I don't
13:43:17 25 necessarily need the slide, but I would like to show the

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13 : 43 : 20 1 graph.

2 THE COURT: Can you do that?

3 MR. O'CONNOR: Do we have a copy of this graph?

4 MR. WOODY: We have the original graph.

13 : 43 : 32 5 THE COURT: Let's get the exhibit number of that,
6 please.

7 MR. O'CONNOR: What's the exhibit number, Greg?

8 MR. WOODY: 876, page 17.

13 : 43 : 41 9 MR. O'CONNOR: I would like to move this into
10 evidence, Your Honor.

11 THE COURT: Is this a demonstrative?

12 MR. O'CONNOR: I would move it into evidence. It's a
13 Bard graph.

14 MR. NORTH: No objection to the admission.

13 : 43 : 50 15 THE COURT: And what is the exhibit number?

16 MR. WOODY: 876.

17 MR. O'CONNOR: 876.

18 THE COURT: All right. 876 is admitted.

19 (Exhibit 876 admitted.)

13 : 43 : 59 20 MR. O'CONNOR: May we display it to the jury?

21 THE COURT: You may.

22 What page are you displaying? What page of 876 are
23 you displaying?

24 MR. WOODY: 17.

13 : 44 : 10 25 MR. O'CONNOR: I'm sorry.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:44:11 1 MR. WOODY: 17. One seven.

2 MR. O'CONNOR: May I proceed, Your Honor?

3 THE COURT: Yes.

4 BY MR. O'CONNOR:

13:44:28 5 Q Dr. McMeeking, have you seen this graph before?

6 A Yes.

7 Q Does this graph stand for the proposition that the G2 is
8 12 times more fracture resistant than the Recovery?

9 A Not quite, because what it shows is that the G2, which is
10 the one that is represented by the yellow box on the right, it
11 takes 11 times as many cycles of loading before it fails
12 compared to the Recovery. So it is actually a factor of 11,
13 not 12.

14 There are some other numbers in documents that are
15 consistent with the number 12, but this particular graph is
16 not consistent with the factor of 12.

17 Q Are you familiar with what Bard called the saluting arm
18 fatigue test?

19 A Yes, I am.

13:45:13 20 MR. O'CONNOR: Can we show Dr. McMeeking Exhibit 876.

21 THE COURT: This is 876.

22 MR. WOODY: What page?

23 MR. O'CONNOR: Page 93 to 97.

24 Is this it?

13:45:34 25 MR. WOODY: That is it.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:45:35 1 BY MR. O'CONNOR:

2 Q Dr. McMeeking, can you explain to the jury what the
3 saluting arm test is.

4 A So the saluting arm test is the one I was just beginning
13:45:42 5 to describe, which is where they took a filter that looks like
6 this, and they cut all of the legs off. So these are the long
7 limbs that are in the filter. So they cut them all off, and
8 they also snipped off the forearm. So the place I would call
9 the elbow, which is where the limb turns the corner, they
13:46:08 10 snipped the forearm off and left only the upper arm on the
11 filter.

12 So now you've got the cap at the top and you've got
13 six struts coming out, more or less like this, from the cap.
14 And this is the cap. So they held the cap in a grip, and then
13:46:31 15 they brought a cylinder up and pushed the arms up by
16 approximately a half inch.

17 So it is like taking an umbrella and inverting the
18 umbrella, and then allowing the umbrella to go back to its
19 original shape.

13:46:49 20 So they carried out this test, and they caused the
21 arms to go up and down until three of them on a filter broke,
22 and they recorded how many cycles of going up and down were
23 required to break the -- each arm. And they then took the
24 average over all the arms, and that led to the results that
13:47:14 25 you see on the screen, which indicates that in the Recovery

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:47:17 1 filter, it only took an average of 57 cycles of going up and
2 down before the arms broke.

3 In contrast, for the G2 filter, in this particular
4 data it took an average of 628 cycles of going up and down on
13:47:36 5 average for the arms to break.

6 Q So is the purpose of the test to see which filter the arms
7 would break faster?

8 A Yes, correct.

9 Q So it sounds like what you're describing is when you have
13:47:49 10 an umbrella and the wind catches it and it goes upside down?

11 A Yes; correct.

12 Q And they do that repeatedly.

13 A Correct.

14 Q And that was the basis for the claim that the Recovery --
13:47:59 15 the G2 was 12 times more fracture resistant than the Recovery?

16 A That's correct.

17 Q Was that appropriate?

18 A No.

19 Q Why not?

13:48:07 20 A Because this represents data for inverting an
21 umbrella-like test on the -- on the filter, and that's all.
22 It doesn't represent anything else about how the filter will
23 behave in terms of its fatigue performance. It doesn't
24 represent how the filter will behave when the vena cava is
13:48:28 25 expanding and contracting, and it will not represent any other

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:48:33 1 ways that fatigue might cause the fatigue -- the filter to
2 fail.

3 Q Dr. McMeeking, are there tests that engineers can use that
4 would prove general fracture resistance?

13:48:46 5 A Yes. The sort of tests that I've been describing where
6 you put the filter in a tube, you expand and contract the tube
7 to represent how the vena cava expands and contracts. You put
8 the filter in tilted, you put it in perforated, you glue it to
9 the wall to represent endothelialization, and you carry out
13:49:10 10 the test and compare how one filter will perform relative to
11 the other.

12 You should also identify any other sources of fatigue
13 that might be a problem. For example, if blood clots come up
14 and hit the filter over and over again, that's potentially
13:49:27 15 another way that fatigue of the filter can occur, and you
16 should carry out all of those bench tests until you've
17 identified all of the ways that fatigue can fail the filter by
18 fracture. And only when you've done that will you know that
19 one filter performs better than another in terms of its
13:49:47 20 fatigue performance.

21 Q Did Bard conduct fatigue-resistant tests to prove that the
22 G2 was 12 times more resistant to fracture than Recovery?

23 A Not in the general sense, no.

24 Q Based upon the tests and the analyses Bard did, is it
13:50:05 25 accurate to claim that the Bard G2 filter is generally 12

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:50:10 1 times more resistant to fracture than the Recovery?

2 A No.

3 Q I'm going to -- I'm almost done here, but I want to ask a
4 question. Medical device companies like Bard hire engineers?

13:50:22 5 A Yes.

6 Q And engineers do tests like what you did; right?

7 A That's correct.

8 Q Are engineers supposed to be there to help that company
9 know how to comply with its responsibilities to put patient
13:50:34 10 safety number one?

11 A Yes. Engineers are hired for their expertise and their
12 knowledge, and they should -- they are required and they
13 should provided advice to the company based on that knowledge
14 and those insights.

13:50:50 15 Q Should engineers that work for a company like Bard, when
16 they see something that's not right, see a test that's not
17 being accurately portrayed, should they report that
18 information to Bard?

19 A Yes.

13:51:05 20 MR. NORTH: Your Honor, I'm going to object. It's
21 outside of the scope of the expertise he's been designated for
22 in the report.

23 THE COURT: Is that in his report?

24 MR. O'CONNOR: Yes, Your Honor. I'm getting to it.

13:51:15 25 E-mail from Micky Graves.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:51:16 1 THE COURT: No. Is the opinion he just stated in the
2 report?

3 MR. O'CONNOR: Is your opinion in the report about
4 the information from Micky Graves?

13:51:24 5 THE WITNESS: Yes.

6 THE COURT: I'm asking you whether the question you
7 just asked him is in the report.

8 MR. O'CONNOR: Well, there are -- there is -- he has
9 opinions in the report about an e-mail that Bard received from
13:51:35 10 an engineer.

11 THE COURT: I just want to know if the opinion you
12 just asked about what a reasonable engineer should do is in
13 the report? And if so, where, so I can confirm.

14 MR. O'CONNOR: Well, I can't point it out now,
13:51:45 15 Your Honor. But I just think he's talked about reasonable
16 engineering standards and practices, and I'm just trying to
17 ask him to just tell the jury --

18 THE COURT: You can't elicit any opinion that's not
19 in the report. So if you, for both sides, ask a question and
13:51:57 20 it's challenged as not in the report, you have to show me
21 where it is in the report. And so I'm going to sustain the
22 last objection.

23 MR. O'CONNOR: May I --

24 THE COURT: The objection to the last question.

13:52:08 25 MR. O'CONNOR: May I ask it a different way?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:52:09 1 THE COURT: Yeah, you can ask whatever questions you
2 choose, but if it's challenged as not in the report, on either
3 side with experts, be prepared to show me where it is in the
4 report.

13:52:18 5 MR. O'CONNOR: Thank you.

6 BY MR. O'CONNOR:

7 Q In this case, did you review and rely on information that
8 was provided by Bard?

9 A Yes.

13:52:24 10 Q Did you review and rely on communications that came from
11 engineering?

12 A Yes.

13 Q Did you come across any evidence in this case where an
14 engineer that worked for Bard discussed the saluting arm test
13:52:37 15 with Bard?

16 A Yes.

17 Q And who that was engineer?

18 A That was Micky Graves.

19 Q And did you report Micky Graves' communication in your
13:52:45 20 report?

21 A I did in my report.

22 Q And why did you do that?

23 A I did that because it represented to me that what Bard was
24 doing was not consistent with the standards of care that
13:52:57 25 should be implemented by an engineering company and by

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:53:00 1 engineers in that company.

2 Q Let me show you Exhibit 1295.

3 Do you see that, Dr. McMeeking?

4 A Yes, I do.

13:53:18 5 Q This is an e-mail from Micky Graves. And do you know who
6 Micky Graves was?

7 A He's an engineer in Bard.

8 Q And what is the subject of the e-mail?

9 A Well, the subject of the e-mail is the saluting arm test,
13:53:34 10 or the inverted umbrella test that I just described.

11 Q And is this an e-mail that you reviewed and relied upon in
12 arriving at opinions that you've reached in this case?

13 A I did.

14 MR. O'CONNOR: At this time I would offer
13:53:47 15 Exhibit 1295 in evidence, Your Honor.

16 MR. NORTH: No objection.

17 THE COURT: 1295 is admitted.

18 (Exhibit 1295 admitted.)

19 MR. O'CONNOR: May we display it to the jury?

13:54:00 20 THE COURT: Yes.

21 BY MR. O'CONNOR:

22 Q Dr. McMeeking, we have Micky Graves, who's a Bard
23 engineer, reporting his concern about the resistant fatigue
24 test, saluting arm test?

13:54:18 25 A He was expressing his concern about that test and

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:54:21 1 associated matters to do with calculations.

2 Q And what was his concern about the test that was done?

3 A His concern was that that -- that they chose to -- chose
4 not to do calculations and -- because they believed it would
13:54:41 5 give them an answer they did not like, that it would show that
6 the filter would be prone to fatigue and that it would have
7 problems in terms of fatigue fracture.

8 Q And is this what you have been talking to the jury about
9 today?

13:54:59 10 A Yes.

11 Q About the inadequate testing from Bard?

12 A Yes.

13 Q And like Micky Graves, is it your opinion that that
14 saluting arm test, the inverted umbrella test, cannot be used
13:55:13 15 to accurately state that the G2 filter was 12 times more
16 fracture resistant than the Recovery?

17 A That's correct, yes.

18 Q And was that a warning that Bard received from its own
19 engineer?

13:55:26 20 A That was indeed a warning that their own engineers gave
21 them.

22 Q And, Dr. McMeeking, are you aware of any evidence in this
23 case where Bard heeded to that warning?

24 A I'm not aware of any evidence that they took that into
13:55:39 25 account.

CROSS-EXAMINATION - ROBERT McMEEKING

13:55:40 1 Q Dr. McMeeking, was the G2 filter out there in 2006?

2 A Yes.

3 Q Was it out there in 2007?

4 A Yes.

13:55:48 5 Q Was it still being put in patients?

6 A Yes.

7 Q And Bard did that knowing that it didn't do the
8 appropriate test.

9 A Correct.

13:55:59 10 Q And it didn't eliminate the problems it saw in the
11 Recovery.

12 A That's correct.

13 MR. O'CONNOR: No more questions.

14 THE COURT: Cross-examination.

13:56:27 15 MR. NORTH: Actually, could we put the last exhibit
16 up, 1295.

17 And could we display it to the jury, Your Honor?

18 THE COURT: You may.

19 C R O S S - E X A M I N A T I O N

13:56:40 20 BY MR. NORTH:

21 Q Good afternoon, Dr. McMeeking.

22 A Afternoon.

23 Q You and I have met on previous occasions.

24 A Yes, we have.

13:56:46 25 Q Before -- since we were on this subject, before we go off

CROSS-EXAMINATION - ROBERT McMEEKING

13:56:48 1 of this subject, what Mr. Graves says towards the end is, "The
2 bigger question, is 12 times more resistant enough?"

3 Isn't that what that document says?

4 A That's correct.

13:57:03 5 Q And doesn't it appear he's questioning, okay, we found it
6 is 12 times better, but is that enough? Should we go further?

7 A That's what he writes in the document.

8 Q Thank you.

9 MR. NORTH: That's all with that document.

13:57:15 10 BY MR. NORTH:

11 Q Dr. McMeeking, based upon your deposition in this
12 proceeding, it is my understanding that you are not going to
13 offer any opinion here that Bard had a higher rate of any
14 particular type of complication relative to its filters than
15 any other manufacturers; correct?

16 A No, I'm not here to testify on that.

17 Q And so you're not here to testify to the relative rates of
18 complications of one filter versus another?

19 A That's correct.

13:57:45 20 Q And you're not here to testify as to the relative
21 complications of one Bard filter against another Bard filter?

22 A No. I'm not here for that purpose.

23 Q Dr. McMeeking, you have not written any publications
24 during your lengthy career on IVC filters specifically;
25 correct?

CROSS-EXAMINATION - ROBERT McMEEKING

13:58:04 1 A That's correct.

2 Q And the few publications that you have written that even
3 deal with medical devices concern heart valves; right?

4 A That's correct.

13:58:17 5 Q And you have never personally designed a medical device.

6 A No, I have not.

7 Q Therefore, you've never designed an inferior vena cava
8 filter.

9 A No, I have not.

13:58:28 10 Q And other than your participation as an expert witness for
11 the plaintiff in this litigation, you have never performed an
12 analysis of an IVC filter; correct?

13 A Other than what I've done for this case, I have not
14 carried out such analysis. However, the analysis is very
15 similar to those that I do carry out for heart valves and
16 stents since their function and their configuration and what
17 they have to deal with when implanted is very similar.

18 Q Well, and I should probably correct my -- the nature of my
19 question.

13:59:06 20 You have also been involved in a case pending against
21 Cook Medical Company as an expert witness for the plaintiff;
22 correct?

23 A That's correct. And so I should have stated that I have
24 done calculations for that case as well.

13:59:20 25 Q And you actually testified in a federal court in

CROSS-EXAMINATION - ROBERT McMEEKING

13:59:24 1 Evansville, Indiana, I believe last October, against Cook
2 Medical Company; correct?

3 A That's correct.

4 Q And Cook Medical Company manufactures at least two
13:59:35 5 inferior vena cava filters, and I think we've heard their
6 names already during this trial, the Celect and the Gunther
7 Tulip; correct?

8 A That's correct.

9 Q And in that courtroom six months ago or so, four months
13:59:48 10 ago, you testified that the Cook filter was defective?

11 MR. O'CONNOR: Objection. Irrelevant, Your Honor.

12 THE COURT: Overruled.

13 THE WITNESS: Yes, that's correct.

14 BY MR. NORTH:

14:00:00 15 Q And were you retained in that litigation by some of the
16 same attorneys that retained you in this litigation?

17 MR. O'CONNOR: Objection. Irrelevant, Your Honor.

18 THE COURT: Overruled.

19 THE WITNESS: Yes, some of them are the same
14:00:12 20 attorneys.

21 BY MR. NORTH:

22 Q You have never been -- other than the calculations and the
23 modeling that you have done in this litigation and the Cook
24 litigation, you have never been involved in the testing of any
14:00:29 25 inferior vena cava filters, have you?

CROSS-EXAMINATION - ROBERT McMEEKING

14:00:31 1 A That's correct.

2 Q And you are not a medical doctor?

3 A I'm not a medical doctor, no.

4 Q And while you're certainly an esteemed mechanical
14:00:42 5 engineer, you are not trained as a biomedical engineer;
6 correct?

7 A Correct, I'm not a biomedical engineer. However, I am a
8 mechanical engineer with a significant interest and activity
9 in the biomedical engineering area.

14:01:16 10 Q Let's talk, if we could, about the calculations you did.

11 As I understand, the calculations you did were all
12 either by hand, sort of mathematical computations like we're
13 all taught in school, or computer modeling; correct?

14 A That's correct.

14:01:33 15 Q You did absolutely no bench testing yourself on any Bard
16 filter; is that correct?

17 A That's correct.

18 Q And you have never done any bench testing on any IVC
19 filter; correct?

14:01:52 20 A That's correct.

21 Q And you have never designed the protocol for any bench
22 testing for an IVC filter; correct?

23 A That's correct.

24 MR. NORTH: If we could look at Exhibit 4349. I
14:02:12 25 believe this was admitted for the plaintiff.

CROSS-EXAMINATION - ROBERT McMEEKING

14:02:14 1 Could we --

2 THE COURT: It's a demonstrative?

3 THE COURTROOM DEPUTY: Yeah.

4 THE COURT: I don't think it was admitted.

14:02:24 5 MR. NORTH: I'm sorry, as a demonstrative. Could we
6 display that to the jury, Your Honor?

7 THE COURT: Yes.

8 BY MR. NORTH:

9 Q This is a demonstrative exhibit you prepared; correct? Or
14:02:36 10 had prepared for your testimony today?

11 A That's correct.

12 Q And this is here to depict the calculations -- not the
13 actual calculations, but the subject of the calculations you
14 did in an effort to measure strain on the Bard filters;
14:02:51 15 correct?

16 A It comes from a calculation in which I looked at the
17 consequences of perforation of the filter through the wall of
18 the vena cava.

19 Q Now, if I understand your calculations correct, and pardon
14:03:07 20 me if I make a mistake because I'm not good in math, you did
21 your calculations on a single arm of a Recovery filter;
22 correct?

23 A In some of the calculations, that's what I did, but not
24 this calculation. This calculation includes all of the limbs
14:03:25 25 of the filter.

CROSS-EXAMINATION - ROBERT McMEEKING

14:03:29 1 Q Of the Recovery filter.

2 A Oh, I'm sorry, I misheard your question.

3 In the case of the Recovery filter, I carried out
4 some calculations with one arm only, and some calculations
14:03:39 5 with two arms.

6 Q You did not do any calculations with the Recovery filter
7 to measure strain that assumed the presence of all 12 legs and
8 arms; correct?

9 A That's correct.

14:03:55 10 Q So all your tests tested only one arm or two arms.

11 A Well, the calculation was carried out for one arm or two
12 arms, but would represent the behavior of all six arms in a
13 situation where the filter is not tilted and is perhaps
14 perforated.

14:04:13 15 Q But you did not conduct any strain calculations assuming
16 all 12 for the entire filter itself; correct?

17 A I think I just said that that's not the case. That when I
18 did the calculation for one or two of the arms, because of the
19 arrangement of the arms, those calculations represented all of
14:04:39 20 the arms, with the legs not playing any role because they were
21 not relevant to the calculations. So the calculations were
22 effective for a filter which had all of its limbs present.

23 Q So you determined that a calculation involving the legs
24 would not be relevant for your purposes?

14:04:59 25 A No, that's not what I said. I said that the legs were not

CROSS-EXAMINATION - ROBERT McMEEKING

14:05:02 1 playing a role in what happened to the arms, and so it was not
2 necessary to calculate what was happening in the legs.

3 Q And I believe that in your calculations you also assumed
4 that the arms of the Recovery filter were penetrating or
14:05:23 5 perforating through the vena cava at least to the length of
6 one elbow; correct?

7 A That's correct, yes.

8 Q And your calculations did not assume that the arm was --
9 just the foot of the arm was perforating through the vena
14:05:40 10 cava; correct?

11 A I should correct myself. In some of my computer
12 calculations, the arm was not perforated through the wall of
13 the vena cava so that the filter or the arms were entirely
14 inside of the wall of the vena cava. But in many of the
14:05:58 15 calculations, the perforation was out to the extent that the
16 elbow was outside of the wall of the vena cava, representing
17 worst case conditions that can arise after perforation of the
18 filter.

19 Q Did you bring your computer calculations here today?

14:06:16 20 A I did not, no.

21 Q Did you bring your hand calculations here today?

22 A The hand calculations are -- the results of them are all
23 in the report that I provided.

24 Q But you didn't bring your computer calculations?

14:06:29 25 A I didn't bring my computer calculations.

CROSS-EXAMINATION - ROBERT McMEEKING

14:06:34 1 Q Now, do you know how often in the real clinical use of
2 these filters you had a Recovery filter, since that's what you
3 did this test on, that has the arm penetrating the inferior
4 vena cava wall all the way up to the elbow or further?

14:06:52 5 A I do not know how often that happens.

6 Q So you don't know whether that happens 2 percent of the
7 time, 10 percent of the time, or 50 percent of the time?

8 A I don't have a percentage that I'm aware of.

9 Q Now, did you do any -- my understanding is you did not do
14:07:09 10 any strain calculations on a G2 filter.

11 A Yes, I did.

12 Q I know you did some tilt calculations. Is it your
13 testimony you also did strain calculations?

14 A I did strain calculations, which are in my report, that
14:07:29 15 are four tables; two of them are relevant to the Recovery and
16 two of them are results for the G2. And those are strain
17 calculations that I did specifically for the purpose of
18 looking at the question of fatigue.

19 Q Okay. And on those calculations, did it likewise assume
14:07:48 20 that the arm was penetrating the wall of the inferior vena
21 cava by at least up to the elbow?

22 A At least up to the elbow, yes.

23 Q And like the Recovery filter calculation, did those G2
24 calculations also involve either just one or two arms?

14:08:05 25 A They involved one or two arms, that's correct.

CROSS-EXAMINATION - ROBERT McMEEKING

14:08:09 1 Representing all six.

14:08:28 2 Q So if I understand what you say, you believed in your
3 mathematical calculations that by modeling one or two arms
4 extending all the way to the elbow, you could then apply those
5 results to all six arms?

6 A That's correct. Yes.

7 Q And you did not believe it necessary to determine how the
8 legs themselves affected that stress?

9 A Well, in the calculations -- in the results that I'm
14:08:44 10 talking about, all six of the arms would be perforated to the
11 same extent, and therefore they would all behave in the same
12 way, so that there would not be any other influence that would
13 modify the results.

14 But I emphasize again that these are worst case
14:08:59 15 results, and they must be taken into consideration. We also
16 know what the best case numbers looked like, and so the real
17 situation, or an actual situation, can lie anywhere between
18 what you would see as the best case and what I identified as
19 the worst case.

14:09:17 20 Q Now, in making these strain calculations, it's my
21 understanding that not only did you assume that the arm had
22 perforated the wall of the IVC all the way to the elbow, but
23 you assumed that it was glued and immobile so that it was not
24 moving back and forth?

14:09:36 25 A I assumed it was endothelialized to the wall, and that

CROSS-EXAMINATION - ROBERT McMEEKING

14:09:40 1 that was a sufficiently strong constraint to limit that kind
2 of motion.

3 Q So there was no motion, so effectively glued, so to speak?

4 A Effectively glued. However, that glueing restricts the
14:09:52 5 rotation. When I have something that is free to rotate, there
6 is no way that stress gets genera- -- strain and stress gets
7 generated. However, if I hold onto my arm and try and turn
8 it, that will generate strain and stress in my arm. And it
9 was that kind of effect I was capturing in the -- by using
14:10:19 10 endothelialization in the calculation. However, it did not
11 restrict the motion of the arm in an absolute way, but rather
12 restricted rotations that might otherwise occur.

13 And, again, I did this because it represents a worst
14 case condition that can arise.

14:10:36 15 Q And I believe you also assumed that the vena cava and the
16 organs surrounding it were stiff enough to hold the arm
17 completely steady so that it did not rotate any; correct?

18 A That's correct in some of the calculations. And the
19 information I have from the literature is that the organs and
14:10:55 20 the tissue around the vena cava can be so stiff that that
21 effect is a real one.

22 Q I believe that you ultimately concluded, based on your
23 calculations, that these strains that you calculate could lead
24 to a rapid failure of the device; correct?

14:11:20 25 A That's correct.

CROSS-EXAMINATION - ROBERT McMEEKING

14:11:21 1 Q And I believe you've told us in testimony before that you
2 believe that rapid failure caused by the strains you found in
3 your calculations could lead to a failure of this device in
4 between one and five respiratory cycles; is that correct?

14:11:40 5 A That's correct. But you must bear in mind that there is
6 time for the conditions to develop. The situation that you're
7 describing that was in my calculation is where the filter is
8 perforated and that -- to a very great extent. And the time
9 that it would take to do that could be a very long time.

14:12:04 10 So the calculation should not be taken to mean that
11 someone who gets a filter would immediately experience a
12 fracture within a few breaths. But once those worst case
13 conditions arise, the levels of strain are so high that indeed
14 the filter would not last very long.

14:12:23 15 Q And I understand your explanation that those conditions
16 may not arise immediately, but under the strains you calculate
17 in that worst case scenario, the filter could fail as quickly
18 as one to five respiratory cycles?

19 A That's right.

14:12:42 20 The worst case conditions, if they all come together,
21 can impose very high strains on the filter, and that was the
22 situation that I identified.

23 Q And, of course, one to five respiratory cycles is one to
24 five breaths; correct?

14:12:58 25 A That's correct.

CROSS-EXAMINATION - ROBERT McMEEKING

14:12:59 1 Q And if this worst case scenario was happening immediately
2 with every filter implanted in a patient, these filters would
3 be failing before the patient ever left the procedure room
4 after the implant; correct?

14:13:11 5 A But I just explained that aspect of the situation, that it
6 takes time for the conditions to develop, and it would be many
7 months or even many years or even longer, or the conditions
8 may never arise in a particular patient. So it's definitely
9 not the case that the failure would occur while the patient
14:13:34 10 was still in the trolley coming out of the operation room.

11 Q And it's my understanding that you are unable to say how
12 often this worst case scenario that you have calculated will
13 actually occur in the real world?

14 A No, I'm not able to give an estimate of that.

14:13:51 15 Q So you don't know whether that worst case scenario will
16 occur in 1 percent of cases, 5 percent of cases, or 50 percent
17 of cases?

18 A No, I'm not able to make that estimate.

19 Q Now, if you had used different assumptions as to how far
14:14:07 20 the arm had penetrated the IVC wall, the calculation of the
21 strain would have been different; correct?

22 A That's correct.

23 Q And the less the arm was penetrating the wall, the lower
24 the strain would have been in all likelihood; correct?

14:14:23 25 A That's correct, yes.

CROSS-EXAMINATION - ROBERT McMEEKING

14:14:24 1 Q And if you had assumed that the arm was not glued to the
2 wall of the IVC, the strains could have been lower, too, in
3 your calculations; correct?

4 A That's correct as well.

14:14:51 5 Q You would agree that specific patient conditions can
6 contribute to whatever occurs with the filter; correct?

7 A Well, in the sense that anatomy varies very greatly over
8 the human population, and so different conditions are going to
9 be encountered in different patients. Different sizes of the
14:15:12 10 IVC, different expansions and contractions of the IVC, and
11 other considerations.

12 Q And there can be thousands, perhaps even millions of
13 different combinations of those conditions surrounding the
14 filter in patients; correct?

14:15:30 15 A I would agree, yes.

16 Q You would agree that a manufacturer does not have to
17 design a product to withstand all worst case scenarios,
18 wouldn't you?

19 A No, they don't need to design devices to withstand all
14:15:45 20 worst case conditions, but take them into consideration and
21 minimize failures and risks to the extent practical.

22 Q And you agree that risks associated with any implantable
23 device cannot be zero; correct?

24 A I doubt that's the case. I -- I'm sorry. I'm agreeing
14:16:05 25 with you. I think that it is very likely that it is

CROSS-EXAMINATION - ROBERT McMEEKING

14:16:07 1 impossible to reduce the risks and failures to zero. It may
2 be possible in some particular cases, but in general I would
3 accept that it is probably not possible.

4 Q And that is why a manufacturer has to design and build a
14:16:24 5 product balancing the risks and benefits of that product;
6 correct?

7 A That's correct.

8 Q And you know that the G2 filter is a second generation
9 retrievable filter manufactured by Bard; correct?

14:16:34 10 A It was ultimately approved. It was cleared for
11 retrieve -- for retrieval eventually, yes.

12 Q And it was the second generation filter of that nature.

13 A It was the second generation filter of that type.

14 Q And you are aware of the fact that Bard made design
14:16:55 15 changes to the original Recovery filter to produce the G2
16 filter?

17 A Yes, there were design changes.

18 Q Now, you have testified that you believe tilt can lead to
19 perforation and even to fracture; correct?

14:17:22 20 A It can contribute to the possibility of fracture, yes, and
21 it can --

22 Q But you have not analyzed what degree of tilt may be
23 necessary to begin this process leading to perforation or
24 fracture; correct?

14:17:35 25 A Well, I've made the assessment that -- that tilt will

CROSS-EXAMINATION - ROBERT McMEEKING

14:17:40 1 cause changes to the forces that the limbs apply to the wall
2 of the vena cava, and therefore will change the rate at which
3 perforation occurs, and that that can contribute to an
4 enhanced process of perforation.

14:17:57 5 Q But my question didn't concern the existence of tilt, it
6 was the degree of tilt. You have not analyzed what degree of
7 tilt, how that may interact with the process leading to
8 perforation or fracture in your opinion?

9 A No, I have not done that.

14:18:13 10 Q And you have not done any bench testing whatsoever to try
11 validate or verify your hypothesis about the interrelationship
12 of tilt, fracture, and perforation; correct?

13 A That's correct.

14 Q The only thing, as I understand, that you have done are
15 hand calculations and computer calculations?

16 A That's correct.

17 Q And that's true with regard to all of these failure modes:
18 Fracture, tilt, perforation; correct?

19 A That's correct, yes.

14:18:50 20 Q And did you do any computer modeling as to migration?

21 A Only in the sense of caudal migration being associated
22 with tilt.

23 Q But, again, the only work you've done there are
24 calculations and computer modeling, and no bench testing?

14:19:08 25 A Correct.

CROSS-EXAMINATION - ROBERT McMEEKING

14:19:14 1 Q And I believe when you testified against Cook, you said
2 that Cook's filters tilt more than any other filters in the
3 marketplace; correct?

4 MR. O'CONNOR: Objection. Hearsay and irrelevant.

14:19:25 5 THE COURT: Overruled.

6 THE WITNESS: I believe that was my testimony.

7 BY MR. NORTH:

8 Q You have not done any analysis or bench testing to compare
9 the G2 filter as a whole to the Recovery filter to identify
14:20:01 10 the extent to which design modifications made to the G2
11 reduced the risks, have you?

12 A Well, I believe I did. For example, I carried out strain
13 calculations for both the G2 and the Recovery, and compared
14 them against each other and found that in many of the
14:20:22 15 circumstances it made little difference, the design changes
16 made little difference going from the Recovery to the G2.

17 Q Would you agree with this statement, which I believe is
18 comparable to something you've stated in your report: All
19 known and foreseeable risks and any undesirable effects should
14:20:50 20 be minimized and be acceptable when weighed against the
21 benefits of the intended performance of medical devices during
22 normal conditions of use.

23 A I have said either that or something very similar, yes.

24 Q Now, you testified earlier that you had not received or
14:21:12 25 seen a certain test that was referenced to you by Mr. O'Connor

CROSS-EXAMINATION - ROBERT McMEEKING

14:21:16 1 in the questioning; correct?

2 A I'm sorry, could you repeat the question.

3 Q You testified earlier that you had not seen a specific
4 test that Mr. O'Connor referenced to you; is that correct?

14:21:27 5 A What I said is I had not seen the report of the test. I
6 haven't seen the test, as well, because I wasn't there, but I
7 haven't seen the report of that test.

8 Q And you relied completely on the plaintiff's attorney to
9 provide you what tests you were given to see; correct?

14:21:42 10 A Well, I asked for all tests, all information, all
11 calculations. All that would be relevant notwithstanding what
12 was in them.

13 Q And the attorneys are the ones that provided those to you;
14 correct?

14:21:55 15 A That's correct.

16 Q Now, I believe you told us that your work here and
17 analysis has been based on calculations and computer modeling,
18 principally on one or two arms of the Recovery filter and the
19 G2 filter, and that you've done no bench testing?

14:22:16 20 A Correct.

21 Q And you have not, therefore, attempted to come up with
22 some alternative design for a filter that you believe would
23 eliminate the problems you have alleged occur with the Bard
24 filters; correct?

14:22:33 25 A I'm not proposing any alternative design. I mean, I've

REDIRECT EXAMINATION - ROBERT McMEEKING

14:22:36 1 described some aspects of a design that -- that it's my
2 assessment would improve the performance in regard to those
3 failure modes, but I've not proposed a specific design.

4 Q Thank you, sir. That's all I have.

14:22:53 5 THE COURT: Redirect?

6 MR. O'CONNOR: Yes, Your Honor.

7 R E D I R E C T E X A M I N A T I O N

8 BY MR. O'CONNOR:

9 Q That test that Mr. North just talked to you about, the one
14:23:09 10 that you and I talked about earlier, do you recall what test
11 that was where there was no report?

12 A Yes.

13 Q What test was that?

14 A That was the test on the Recovery filter where they put
14:23:19 15 the filter in a tube and compressed it and expanded the tube
16 by one millimeter for 32 to 36 million times.

17 Q All right. And you've received the defense experts'
18 reports; right?

19 A I've received many defense experts' reports.

14:23:40 20 Q Have you ever sign a single expert or single expert report
21 that indicated that their own experts received any so-called
22 test report that you just got cross-examined on?

23 A I haven't seen any information that indicated that.

24 Q I mean, certainly if you saw that, you'd say let me see
14:23:58 25 that.

REDIRECT EXAMINATION - ROBERT McMEEKING

14 : 23 : 59 1 A Yes, I would. Yes.

2 Q And, Dr. McMeeking, when you did your calculations, was
3 there any reason to do bench testing after that?

4 A No. Since I used methods that -- which are completely
14 : 24 : 12 5 standard, completely accurate, and completely reliable, there
6 was no need to carry out bench tests to validate my
7 calculations.

8 And I also had access to reviewing those bench tests
9 that were carried out by Bard and by Dr. Briant, and I looked
14 : 24 : 33 10 at them in comparison to my calculations.

11 Q How many documents would you say you've reviewed that have
12 come from Bard?

13 A Thousands, I would say. Certainly thousands of pages.

14 Q And you've seen all sorts of documentation about problems
14 : 24 : 53 15 they've had with the Recovery and the G2?

16 A That's correct.

17 Q So let's just talk about what you've seen.

18 Have you seen evidence in your case of patients
19 getting hurt by these filters?

14 : 25 : 06 20 A Yes.

21 Q Have you seen that these filters, the Recovery and the G2,
22 have done exactly what your tests have shown?

23 A Yes, I have seen lots of information that indicates that.

24 Q So Bard tests the best case scenario and you test the
14 : 25 : 25 25 worst case scenario.

REDIRECT EXAMINATION - ROBERT McMEEKING

14:25:26 1 A Correct.

2 Q What's the reality? What's happened out there to the
3 patients that got these filters?

4 A Well, the reality is that the events that I'm describing
14:25:35 5 do occur, and the conditions are bad enough that the
6 consequences that I'm describing, such as fracture of the
7 filter, is occurring.

8 Q The calculations you've done, would you hope -- could Bard
9 use those if they wanted to make a safe filter?

14:25:56 10 A They can have them. They already have possession of them.
11 I assume they can use them as they see fit.

12 Q The calculations that you did?

13 A Yes.

14 Q Were they calculations Bard could have done back in 2002,
14:26:07 15 2003, 2004, 2005?

16 A Yes.

17 Q The calculations that you did, Dr. McMeeking, would those
18 calculations have told Bard that if they put their filter, the
19 Recovery and the G2, on the market, they are going to hurt
patients?

21 MR. NORTH: Objection, Your Honor. Argumentative.

22 THE COURT: That was argument. Rephrase the
23 question, please.

24 MR. O'CONNOR: Sure.

25

REDIRECT EXAMINATION - ROBERT McMEEKING

14 : 26 : 30 1 BY MR. O'CONNOR:

2 Q Did the calculations you performed, if you had done those
3 back in time, would they have predicted that patients would
4 have been hurt, injured, and come close to death from the
14 : 26 : 44 5 Recovery and the G2?

6 A Yes.

7 Q The calculations that you did, had you done them back at
8 the time of the Recovery and you gave them to Bard, would you
9 expect that that filter would not have been put out in the
14 : 26 : 59 10 market?

11 A I would expect the Recovery would not have been put on the
12 market, and that they would have redesigned it to eliminate
13 the foreseeable failure modes.

14 Q Would the calculations that you did, Dr. McMeeking, have
14 : 27 : 12 15 told a reasonable medical device company not to put that
16 device on the market because it may hurt somebody, it may hurt
17 a Sheri Booker down the road?

18 A Yes.

19 Q And if you had the opportunity, would you have taken it
14 : 27 : 28 20 and stopped this?

21 A If I had the opportunity, I would have advised Bard that
22 this was a bad filter, that they should not proceed with
23 marketing it.

24 Q Has that been your message to Bard in the reports you've
14 : 27 : 44 25 given in this case?

14:27:45 1 A Yes.

2 Q To stop?

3 A Yes.

4 MR. O'CONNOR: No further questions.

14:27:53 5 THE COURT: What did you say, Mr. O'Connor?

6 MR. O'CONNOR: Excuse me?

7 THE COURT: I didn't hear what you said.

8 MR. O'CONNOR: I said I have no more questions.

9 Thank you, Your Honor.

14:28:00 10 THE COURT: All right.

11 We're going to take a break, ladies and gentlemen.

12 We'll resume at a quarter to.

13 You can step down, sir.

14 (The jury exited the courtroom at 2:28.)

14:28:37 15 THE COURT: All right. We'll take a break for 15
16 minutes. Thank you.

17 (Recess taken from 2:28 to 2:45. Proceedings resumed in
18 open court with the jury present.)

19 THE COURT: Thank you, please be seated.

14:45:59 20 Counsel, your next witness.

21 MR. LOPEZ: Yes, Your Honor. May I approach the
22 podium?

23 At this time plaintiffs are going to call by
24 videotape deposition Natalie Wong, who is currently employed
14:46:18 25 at Bard Peripheral Vascular and since 2008 has been a quality

VIDEOTAPED DEPOSITION OF NATALIE WONG

14:46:23 1 engineering manager in field assurance.

2 Ms. Wong earned a bachelor's degree in industrial
3 engineering --

4 THE COURT: Let me interrupt four a minute,
14:46:31 5 Mr. Lopez.

6 MR. LOPEZ: I'm sorry, Your Honor.

7 THE COURT: I assume this is the joint background
8 piece?

9 MR. LOPEZ: Yes, sir. We've agreed on this.

14:46:36 10 THE COURT: Ladies and gentlemen, what the attorneys
11 have done to shorten the amount of videotape deposition you
12 need to watch is with respect to witnesses like Ms. Wong,
13 they've agreed on a short background description of her. So
14 you can accept what is read to you about the witnesses as
14:46:52 15 true. That way we don't have to play that part of the
16 transcript and you can get right into the substance.

17 Go ahead, Mr. Lopez.

18 MR. LOPEZ: Thank you, Your Honor.

19 Ms. Wong earned a bachelors degree in industrial
14:47:03 20 engineering in 2001 and a masters in business administration
21 in 2007 from Arizona State University. She began working at
22 BPV in April of 2002 as a quality engineer and has been with
23 the company since, with the exception of a brief stint at
24 Lockheed Martin in Georgia.

14:47:22 25 At BPV she handles quality assurance issues and

VIDEOTAPED DEPOSITION OF NATALIE WONG

14:47:26 1 conducts trending analysis related to BPV's IVC filters.

14:47:46 2 And, Your Honor, at this time, with agreement of
3 counsel, we've got a number of exhibits that we'd like to move
4 into evidence. And I can read to the jury the exhibit number
5 that they will hear on the video and also give them a trial
6 exhibit number. Would you like me to do that now?

7 THE COURT: Yes, please. Could you do them in
8 reverse order, though, trial number and then video number.

9 MR. LOPEZ: Yes, sir.

14:48:02 10 Trial Exhibit Number 2243 is Wong Exhibit 537 in the
11 deposition.

12 Exhibit 2244 -- I should say Trial Exhibit 2244 is
13 Deposition Exhibit 538.

14 Trial Exhibit 2057 is Deposition Exhibit 539.

14:48:28 15 Trial Exhibit 2245 is Deposition Exhibit 540.

16 Trial Exhibit 2246 is Deposition Exhibit 541.

17 Trial Exhibit 2247 is Deposition Exhibit 542.

18 Trial Exhibit 2248 is Deposition Exhibit 543.

19 Trial Exhibit 2249 is Deposition Exhibit 544.

14:49:05 20 Trial Exhibit 2250 is Deposition Exhibit 545.

21 Trial Exhibit 2052 is Deposition Exhibit 546.

22 Trial Exhibit 2251 is Deposition Exhibit 547.

23 And, finally, trial Exhibit 2253 is deposition
24 Exhibit 549.

14:49:33 25 At this time plaintiffs would like to move those

VIDEOTAPED DEPOSITION OF JANET HUDNALL

14:49:35 1 trial exhibits into evidence, Your Honor.

2 MS. HELM: No objection, Your Honor.

3 THE COURT: All right, those will all be admitted
4 into evidence.

14:49:44 5 MR. LOPEZ: And allowed to be displayed on the video?

6 THE COURT: Yes.

7 MR. LOPEZ: Thank you.

8 (Exhibits 2243, 2244, 2057, 2245, 2246, 2247, 2248, 2249,
9 2250, 2052, 2251, and 2253 admitted.)

14:49:50 10 (Video deposition played.)

11 MR. LOPEZ: That concludes her testimony, Your Honor.

12 THE COURT: All right.

13 MR. LOPEZ: We have another deposition to play, Your
14 Honor. We won't get through it, but we'll get started.

16:11:36 15 THE COURT: Okay.

16 We'll go to 4:30, ladies and gentlemen, then break.

17 MR. LOPEZ: This is the deposition of Janet Hudnall.

18 Janet Hudnall has a degree in industrial engineering
19 from the Georgia Institute of Technology, and an MBA from ASU.
20 She began working for what became Bard Peripheral Vascular in
21 June 1998 as a product development engineer and was promoted
22 so senior product manager in 2002 and marketing manager in
23 2004.

24 As marketing manager, Ms. Hudnall managed marketing
16:12:09 25 activities of BPV's IVC filter product line and was involved

VIDEOTAPED DEPOSITION OF JANET HUDNALL

16:12:15 1 in the launch of both the Recovery filter and the G2 filter.

2 Ms. Hudnall left BPV in 2008 and since then has
3 worked in marketing for several medical device manufacturers.

4 And then, Your Honor, may I provide the Court and the
16:12:36 5 jury the exhibits, trial exhibits, and corresponding
6 deposition exhibit.

7 Trial Exhibit 1053 is Deposition Exhibit 20.

8 Trial Exhibit 1335 is Trial Exhibit -- I'm sorry, is
9 Deposition Exhibit 21.

16:12:54 10 Trial Exhibit 1336 is Deposition Exhibit 22.

11 Trial Exhibit 1337 is Deposition Exhibit 23.

12 Trial Exhibit 545 is Deposition Exhibit 35.

13 Trial Exhibit 1339 is Deposition Exhibit 29.

14 Trial Exhibit 1594 is Deposition Exhibit 34.

16:13:33 15 Thank you, Your Honor.

16 THE COURT: Are you moving those into evidence?

17 MR. LOPEZ: Yes, Your Honor. Moving those trial
18 exhibits into evidence.

19 THE COURT: Any objection?

16:13:41 20 MS. HELM: No, Your Honor.

21 THE COURT: All right. Those exhibits are admitted.

22 (Exhibits 1053, 1335, 1336, 1337, 545, 1339, and 1594
23 admitted.)

24 (Video deposition played.)

16:13:59 25 THE COURT: Let's stop the depo at this point.

16:29:39 1 All right, ladies and gentlemen, we've reached 4:30
2 so we'll break for the week. Remember we're not here Monday.
3 We'll plan to start Tuesday morning.

4 My battery's dead. I'll try to raise my voice.

16:29:53 5 We'll plan to start Tuesday morning at 9 o'clock. It
6 will be important over the weekend, obviously, you not talk
7 about the case or do any research. Keep an open mind. We'll
8 get started Tuesday at 9 o'clock.

9 Counsel, anything else we before we excuse the jury?

16:30:09 10 MR. NORTH: Nothing further, Your Honor.

11 MR. O'CONNOR: Nothing.

12 THE COURT: Okay. Have a good weekend. We'll see
13 you on Tuesday.

14 (The jury exited the courtroom at 4:30.)

16:30:42 15 THE COURT: Counsel, how have you divided the time on
16 the Wong deposition?

17 MR. LOPEZ: I just wrote it down.

18 Did you write it down, Kate?

19 MS. HELM: Yeah.

16:31:06 20 MR. LOPEZ: I have 105 for us and 15 for you?

21 MS. HELM: That's exactly what I have.

22 MR. LOPEZ: Okay. We wrote down the same numbers 105
23 for plaintiff and 15 -- one hour five minutes for plaintiff,
24 15 minutes for the defense.

16:31:20 25 THE COURT: All right. 15 minutes. Okay. Give me

16:31:23 1 just a minute. I'll give your total time.

2 MR. LOPEZ: That was for Wong, Natalie Wong.

3 THE COURT: Right. I can't factor in Hudnall until
4 we finish.

16:33:01 5 Okay. As of this evening, not adjusting for Hudnall,
6 plaintiffs have used ten hours and 48 minutes; defendants
7 three hours and 30 minutes.

8 And the total time we've used is 33 minutes ahead of
9 schedule. So by going a little longer each day, we've gained
16:33:26 10 33 minutes on what we're needing to do.

11 What do you have on the Simon Nitinol issue for me to
12 look at?

13 MR. LOPEZ: Did we give --

14 You have it on thumb drive, Your Honor.

16:33:45 15 MR. NORTH: Your Honor, we provided you with a thumb
16 drive of the medical articles that we're using, relevant
17 portions of the expert reports on both sides that reference
18 these articles, and also there was some question about
19 complaint data. We provided the spreadsheets of all the
16:34:03 20 complaint data that's long been produced in the cases. I know
21 you don't want to look through that in detail. It's there.

22 I would note some of the fields are hidden, so you
23 have to sort of click on them to get into the weeds. But I
24 don't think that's what the Court's interested in.

16:34:19 25 THE COURT: How about from the plaintiff?

16:34:21 1 MR. LOPEZ: Did you get ours?

2 THE COURTROOM DEPUTY: No.

3 MR. LOPEZ: Your Honor, there's a lot of data there.

4 I'm thinking just probably for your sake more than anyone, if
16:34:35 5 we got here at 8:30, we could -- I could just walk you through
6 in ten minutes my position regarding what's on there and our
7 position regarding SNF issue.

8 THE COURT: So what's on here?

9 MR. LOPEZ: How many documents? Ten documents. Ten
16:34:56 10 or 11 documents showing Bard's use of SNF and this whole
11 statistical -- I mean substantial equivalence issue and how
12 they use it in their 510(k), and now they're going to start
13 introducing stuff that's -- I mean, it's just not part of it.

14 THE COURT: Is it highlighted in some way?

15 MR. LOPEZ: I think it's bookmarked. I think someone
16 bookmarked it.

17 Is it bookmarked?

18 I was told by our paralegal who was working on it
19 that she bookmarked the pages or the areas --

16:35:26 20 THE COURT: Are they highlighted so I can tell what
21 you're focusing me on or do I just have ten big documents?

22 MR. LOPEZ: When I say bookmarked, it takes you to
23 the page. I wish she was here.

24 Is Felice here?

16:35:42 25 MR. NORTH: Your Honor, would it be of any help to

16:35:43 1 you if both sides prepared a two-page not brief but
2 explanation what's there on issue and submit it by midday
3 Monday?

4 THE COURT: Probably, yeah.

16:35:56 5 MR. NORTH: Why don't we do that. By noon on Monday?

6 THE COURT: Each side two pages?

7 MR. NORTH: Yes.

8 THE COURT: Instead of attaching it. Yeah, if you
9 file that by midday Monday, I've got -- I won't look at it
16:36:08 10 until Monday night because I've got 13 criminal hearings
11 Monday afternoon. But I'll look at it Monday night. If I've
12 got issues to ask we'll talk about it on Tuesday morning.

13 Please remember over the weekend to look at the jury
14 instructions and verdict form. We'll plan to talk about
16:36:27 15 those, I think, on Thursday after the hearing.

16 MR. LOPEZ: That was after the -- afternoon?

17 THE COURT: Yeah. 4:30 Thursday we'll talk about
18 jury instructions.

19 MR. LOPEZ: Have a good weekend.

16:36:43 20 THE COURT: Thank you.

21 (End of transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 16th day of March,
2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter